

(g) *Labeling.* A method of verifying that all items prepared for disposal have been decontaminated will be established for etiologic agent wastes. Mixed waste will be labeled as appropriate to indicate the hazards that must be addressed after decontamination.

(h) *Recordkeeping.* A manifest will be initiated and maintained, where required, to record the disposition and transfer of waste. Applicable Federal, State, and local ordinances will be followed.

### Subpart F—Importation, Shipment, and Transport of Etiologic Agents

#### § 627.35 Introduction.

The CDC of the Public Health Service (PHS), the United States Department of Agriculture (USDA), the Food and Drug Administration (FDA), the Department of Transportation (DOT), the United States Postal Service and the International Air Transport Association (IATA) regulate the importation, shipment, and transportation of etiologic agents. This chapter outlines the minimum administrative requirements the commander or institute director are to follow and gives sources for information on the requirements for importation, packaging, labeling, and shipment of etiologic agents.

#### § 627.36 Administration.

The commander or institute director will establish the following controls to ensure that etiologic agents are transported with proper authorization, controls, and procedures:

(a) Institute policies will be established in writing to ensure that before etiologic agents are acquired or shipped—

(1) The division chief responsible for the area where work with etiologic agents is to be conducted approves all acquisitions or shipments.

(2) The safety officer is informed in writing of the type and amount of any BL-4 or USDA-restricted etiologic agent (listed in HHS publication No. (NIH) 88-8395 or current edition) being received, and the estimated date of arrival.

(3) The recipient of all etiologic agents shipped from an institute will be documented.

(4) The commander or institute director approves all acquisitions and shipments of BL-4 or USDA-restricted etiologic agents.

(5) The commander or institute director approves all requests for shipments to or from foreign countries and to individuals not affiliated with an institution or agency (for example, physicians in private practice).

(6) The Office of The Surgeon General, United States Army, or the Commander, United States Army Materiel Command (AMC) approves the initial acquisition and use of all reference stocks of etiologic agents and transfers between Army RDTE activities in accordance with AR 70-65.

(7) There is full compliance with the regulatory requirements referenced in §§ 627.37, 627.38, 627.39 and 627.40.

(8) The following information regarding the recipient and the intended use of BL-4 and USDA-restricted animal pathogens, will be kept on file for 10 years. This information will also be kept for all shipments to or from foreign countries and to individuals not affiliated with an institution or agency (for example, physicians in private practice).

(i) The requester's name and address.

(ii) The type and amount of the etiologic agent to be sent.

(iii) The qualifications of the recipient of the etiologic agent.

(iv) The intended use of the etiologic agent.

(v) A statement indicating that the agent is not for human use.

(b) Etiologic agents assigned to biosafety level 1, 2, or 3, approved for shipment, and properly labeled and packaged may be shipped by commercial cargo carriers.

(c) All etiologic agents assigned to BL-4 or USDA-restricted animal pathogens approved for shipment and properly packaged, will be accompanied by a designated courier, or under close supervision of a responsible party who will monitor aspects of the shipment, ensuring that required transfers have been completed and documented and final receipt has been accomplished and acknowledged.